

EXHIBIT 8

CASSAVA SCIENCES: GAME OVER!

Cassava Sciences (SAVA): Game over!

A warning for the US healthcare system

Report by Quintessential Capital Management
Wednesday, November 3, 2021



CASSAVA SCIENCES: GAME OVER!

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QCM is SHORT the stock of Cassava Sciences (SAVA)
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Executive Summary

Quintessential Capital Management (QCM) has performed an in-depth study into Cassava Sciences (Nasdaq: SAVA), a U.S. biotech firm ostensibly developing Simufilam, a “disease modifying” drug for the treatment of Alzheimer’s Disease, currently in phase II of clinical trials.

We have targeted Cassava and its affiliates for months with a thorough investigation including infiltration of undercover investigators into its clinical research centers, surveillance of its research facilities, background checks on the actors involved, and multiple expert opinions from industry leaders.

After reviewing the information in its entirety, **we are of the opinion that Cassava Sciences could be a scheme orchestrated by management to enrich itself at the expense of shareholders, patients, and the US Federal Government.** The approval of an **outrageous** compensation policy, blatantly rewarding short term stock price appreciation (“pump & dump”) may have provided a clear incentive for management to engage in this reckless behavior.

Simufilam, Cassava’s only prospective drug, appears **based on allegedly forged scientific research.** Phase II trials have been conducted with **numerous and serious irregularities** which appear to have allowed management to deceive investors about the effectiveness of the drug.

In our opinion, **Simufilam is a worthless compound**, and any touted benefit is the likely the result of a combination of **forgery**, “**cherry picking**” of patients and statistical **manipulation of data**, of which we have plenty of disturbing evidence.

This alleged exercise in deception has taken place with the involvement of an astounding number of **questionable characters**: Cassava’s former Senior Clinical Research Associate is a **convicted felon with**

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a record in fraud and theft. Cassava's prominent clinical research site (whose CEO is coauthor of critical research on Simufilam), IMIC Inc., is co-owned by a **former escort, stripper and crack addict with a criminal record for consumption and possession of cocaine.** IMIC's Principal Investigator has been hit with a rare and ominous **FDA warning letter** during recent trials. Cassava's CEO and CMO have been caught making allegedly **fraudulent statements** about Simufilam's predecessor Remoxy, which duly failed, devastating shareholders. Cassava's recent board addition, Richard Barry, has been **involved with multiple frauds**¹.

In several years of fraud-busting we have rarely come across a more blatant and costlier exercise in deception than Cassava. Besides threatening shareholders' funds, Cassava is diverting patients, resources and conspicuous government funds from legitimate studies toward a drug which we believe is useless and **doomed to fail** under the closer scrutiny of phase III trials, if it ever gets there.

If our allegations are substantiated, we believe Cassava's behavior might constitute **securities fraud, FDA fraud and a violation of the False Claims Act.** As such, we have alerted all relevant federal institutions which have received a copy of this report.

We believe that Cassava's stock is worthless, and we assign it a target price of 0 (zero).

¹ See further in the reports for details on the frauds and suspected frauds we refer to.

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Quintessential and its goals

We are an American hedge fund based in New York City. Our main activity consists in identifying, investigating and exposing fraud and criminal conduct in public companies around the world.

We use state-of-the-art investigative techniques and only act after acquiring overwhelming evidence to substantiate our claims. Since 2015, we have completed over ten short activist campaigns exposing various dishonest companies with a 100% success rate.²

In July 2019, our in-depth report named “*A Parmalat in Bologna*” led to the collapse of the Italian €1.1b-unicorn **Bio-on S.p.A.** and the arrest of the executives involved.

In May 2018 our campaign against the Greek retailer **Folli Follie** led to the collapse and de-listing of the company in just three weeks. The perpetrators are currently behind bars.

In December 2018, our action against **Aphria**, a Canadian cannabis company with a market cap of more than \$4 billion, led to the immediate collapse of the stock and the dismissal of the entire board of directors.

In 2015 our report entitled “**A Greek Parmalat**” on Globo Plc led to the immediate collapse of the stock, bankruptcy of the company and resignation of the executives involved, who promptly admitted their guilt.

We also recently exposed fraud at **Akazoo**, a Nasdaq-listed music streaming provider. The stock collapsed, was delisted, and management was successfully sued by the Securities and Exchange Commission.

Our intervention against **Penumbra**, a US medical device manufacturer, has led to an immediate FDA recall of the product we denounced as deadly (stock price duly dropped 36%).

We are a commercial enterprise, and we work for profit. However, we firmly believe in the moral character of our work, which has the effect of removing dishonest companies from the markets. These “bad apples” take financial and human resources away from legitimate companies and harm both shareholders and the general public.

²In virtually all cases our theses have been confirmed by official inquiries. In several cases, the management of the target companies and/or the board of directors has been dismissed. In two cases, the companies ceased to exist weeks after our intervention.

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About Cassava sciences

Cassava Sciences is a US biotech firm domiciled in Austin, Texas. The Company has a market capitalization of \$2bn, zero revenue and loses approximately \$13m per year. Until recently it was staffed by only 11 employees³. The company is led, among others, by Remi Barbier (CEO), Lindsay Burns (SVP) and Nadav Friedmann (CMO).

Cassava's only "asset" is Simufilam, which it describes as a "disease modifying"⁴ drug for the treatment of Alzheimer's Disease, currently in phase II clinical trials.

Until 2019 the company used to be called "Pain Therapeutics". Its only asset then was Remoxy, a pain killer that ultimately failed to gain FDA approval. Both **Mr. Barbier and Mr. Friedman were sued for securities fraud⁵ for their misleading statements about Remoxy's prospects.**

It is curious to observe that "*Cassava*" is actually Mr. Barbier's home address, that the name "*Remoxy*" has likely been taken from Barbier's first name (Remi) and that Mrs. Burns is the wife of Mr. Barbier.

Recent Events

A well-known law firm Cassava recently filed a a "Citizen Petition" with the FDA complaining of "*grave concerns about the quality and integrity of the scientific data supporting Cassava's claims for Simulifam's efficacy*" and soliciting an audit of the existing activity.

QCM investigation and methodology

We have had multiple experts review the "Citizen Petition" and found it highly credible. However, upon reviewing Cassava's claims, we became convinced that the alleged deception could not have been limited

³ Source: CapitalIQ. Recently Cassava hired additional staff as LinkedIn lists some 32 employees

⁴ Nadav Friedmann CMO: "'Today's data with simufilam suggests disease modification,'" added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide transformative treatment benefits following 9 months of dosing." – Press release, July 2021

⁵ We understand that the lawsuit was settled out of court

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to the laboratory analysis mentioned in the complaint⁶. Instead, we suspect that *the entire clinical research process might have been tainted by deception and misconduct*, especially the Simufilam clinical trials.

We proceeded with the goals of probing the legitimacy of the clinical trials, studying management's incentives, and understanding the nature of the actors involved. Specifically, our activity included the following:

- Thorough review of Cassava's history and track record
- Open-Source Intelligence collection on Cassava's staff and its affiliates
- Direct surveillance of facilities and clinical research centers
- Infiltration of undercover investigators in Simufilam clinical research process
- Declarations of former employee of Cassava's and its clinical research centers
- Expert opinions from scientists, investigators and forensic experts

Perverse incentives

There are powerful incentives for Cassava's management to possibly commit misconduct in clinical trials, deceiving investors about the real prospects of Simufilam.

The field of Alzheimer's Disease is well suited for a "pump & dump" scheme: first, because of the giant size of this untapped potential market, even a small probability of a successful drug can result in a large stock market valuation (in this case exceeding \$2.3bn). Second, due to the few existing treatments for Alzheimer's, regulators may be more lenient with new drugs, even those with doubtful efficacy. Third, the very slow progression and difficulty in diagnosing of Alzheimer's Disease may facilitate a deliberate obfuscation of clinical trial results.

⁶ In its presentation to investors, for example, Cassava claimed improvement in cognitive functioning for Simufilam: those could not have been faked through the forgery described in the complaint.

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Moreover, Cassava's management has somehow managed to approve what looks to us like an **outrageous compensation system**, literally rewarding short-term stock price fluctuations regardless of more traditional metrics as such as profitability or drug approval milestones.

The plan rewards management if Cassava's stock reaches certain market capitalization thresholds and holds them for a period of only 20 days. Bonuses range from \$10m to \$50m per threshold and the thresholds range from \$200m to \$5bn. Intermediate amounts, unsurprisingly have not been disclosed, but we estimate the **total bonus pool to be around \$450m**. Clearly management would get rich temporarily inflating Cassava's stock price by creating unlikely expectations for the prospect of its only drug, Simufilam. Should the drug then fail to deliver, and we think it will, shareholders will be wiped out, but management will get to keep their large bonuses.

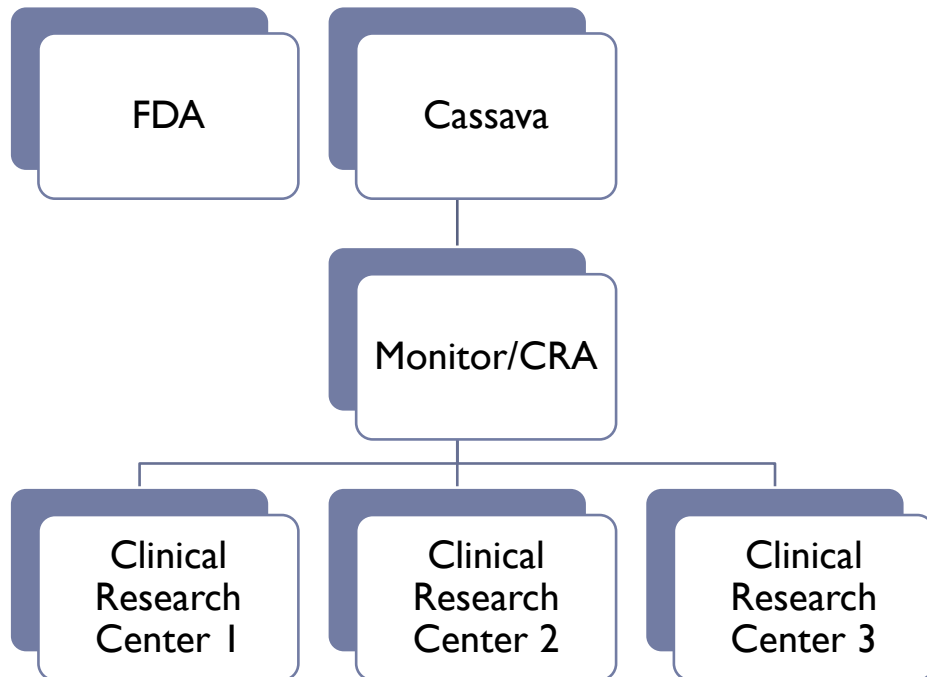
Target Valuation Mil	Aggregate Bonus Payment
\$200,000,000	10,000,000
\$[***]	<i>13,300,000</i>
\$[***]	<i>16,600,000</i>
\$[***]	<i>19,900,000</i>
\$[***]	<i>23,200,000</i>
\$[***]	<i>26,500,000</i>
\$[***]	<i>29,800,000</i>
\$[***]	<i>33,100,000</i>
\$[***]	<i>36,400,000</i>
\$[***]	<i>39,700,000</i>
\$[***]	<i>43,000,000</i>
\$[***]	<i>46,300,000</i>
\$[***]	<i>49,600,000</i>
\$5,000,000,000	\$50,000,000
total	\$437,400,000

Cassava's management peculiar compensation system (figures in italic are estimates) [source: Cassava's official filings]

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Bad actors: Fraudsters as watchdogs of clinical trials?

The alleged, generalized misconduct at Simufilam trials could not have been possible without the presence of people of questionable character involved at every level of the process. Indeed, **we have never detected a higher concentration of felons, fraudsters, and generally incompetent people around any public company**, let alone a healthcare one. In order to understand the ubiquity of Cassava's "bad actors" problem, it is helpful to review the following slide, which shows how the link between the sponsor (e.g. Cassava) and the sites conducting the trials is mediated by the Clinical Research Associate (CRA) or monitor.

CLINICAL RESEARCH PROCESS FLOW CHART


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The CRA has a key role in the process acting as “watchdog”:

“A clinical research associate ensures compliance with the clinical trial protocol, checks clinical site activities, makes on-site visits, reviews case report forms (CRFs), and communicates with clinical research coordinators.[4] Clinical research associates also “ensure the protection of the rights, safety and well-being of human study subjects.”[5] Additionally, a CRA must “make certain that the scientific integrity of the data collected is protected and verified” and “ensure that adverse events are correctly documented and reported.”[5]”

It is astounding that, for the trials at Cassava, such a role has been assigned to the following individual:

*Convicted fraudster and felon **Hilda *****⁸ a.k.a. Hilda ***, CRA of Cassava Sciences*



Texas Department of Public Safety
Criminal History Search

SERVER: DPSWEBMASTER DATE: 9/20/2021 9:41:58 AM
LANG: ENGLISH (UNITED STATES) ORIG: PublicSite

Criminal History Conviction Search

Search Information


BATCH # 5506835
SEARCH # 25853102
SEARCH SUMMARY [REDACTED] HILDA [REDACTED]
DATE 2021-09-20T09:41:57.9086614-05:00


[REDACTED], HILDA [REDACTED] (SID: 07099282)

SID 07099282
DATE LAST UPDATED 6/30/2021
SEX FEMALE
RACE WHITE
ETHNICITY HISPANIC
HEIGHT 5'1"
WEIGHT 150 LBS
EYES BROWN
HAIR BROWN
PLACE OF BIRTH TEXAS
NAME(S) [REDACTED] HILDA [REDACTED]
[REDACTED] HILDA [REDACTED] (PRIMARY)
BIRTH DATE(S) 3/13/1958 (PRIMARY)

ARREST SUMMARY


DATE OF ARREST	SEQUENCE CODE	TRACKING NUMBER	AGENCY DESCRIPTION
5/22/2003	A	9076831939	DALLAS COUNTY SHERIFFS OFFICE
9/9/2013	A	9181201680	IRVING PD





Hilda [REDACTED]
Sr Clinical Research Associate III
The University of Texas at Dallas
Irving, Texas, United States
Pharmaceuticals · 500+ 28

Add phone number
Public profile Search on Bing
Save to project



Sr. Clinical Research Associate
Pain Therapeutics, Inc.
Oct 2018 – Feb 2019 · 4 mos
Dallas, Texas

⁷ Source: Wikipedia. Individual citations are clickable for source documents

⁸ The subject's actual identity has been redacted for privacy

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COURT DISPOSITION DATE	6/13/2014
DATE OF SENTENCE/STATUS	6/13/2014
CAUSE NUMBER	CAU:F-1334891
FINAL PLEADING	GUILTY (G)
COURT CONFINEMENT	2Y
COURT PROBATION	3Y
COURT FINE	1500
COURT COSTS	244
AGENCY RECEIVING CUSTODY	CRIMINAL DISTRICT COURT #3 OF DALLAS CO DALLAS (TX057045G)

Hilda resides in *** Texas. According to her LinkedIn profile (see above), she worked on behalf of Cassava Sciences as senior CRA between 2018 and 2019⁹. She claims studies at the University of Texas (which according to the registrar’s office may be false¹⁰), and a certificate as Registered Medical Assistant, which we similarly failed to find in her public records¹¹. Her online resume appears apparently heavily plagiarized from [this one](#).

More worryingly, we found a criminal and arrest record for Hilda, including a **felony for theft** (for which she appears to have served two years in prison) and a **Class A misdemeanor for “fraudulent activities”**, apparently for defrauding unemployment insurance. Based on her record, she might even have been on probation while working for Cassava as senior CRA!

According to our sources, Hilda may have been substituted as monitor by Mr. Nadav Friedman, Cassava’s CMO, who has been caught making allegedly [fraudulent statements](#) along with Remi Barbier regarding Cassava’s previous, failed drug. More on this later. It is superfluous to point out that assigning the role of primary watchdog first to a serial liar and convicted felon, then to a company insider with a record of securities fraud and in conflict of interest, does not bode well for the legitimacy of the Simufilam trials and may explain the irregularities that we have identified earlier.

⁹ We ruled out the possibility that Hilda may have lied about her work for Cassava since her LinkedIn profile shows she is a first-level connection with multiple employees of one of the clinical sites used for Simufilam

¹⁰ We reached out to the university’s registrar’s office which could not find her name in the system. The subject using multiple aliases so we can’t rule out that she might have been registered under a different name.

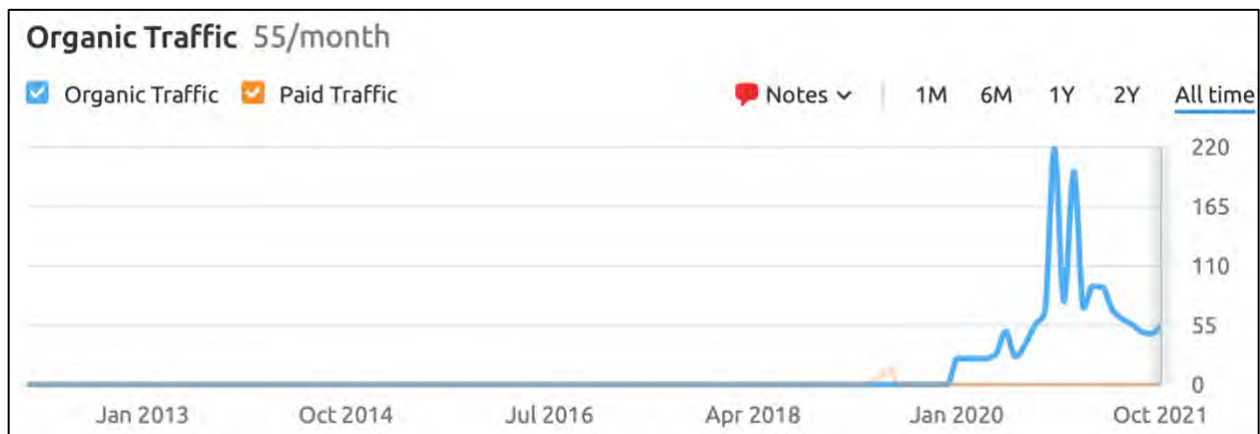
¹¹ We used Thomson Reuter’s “Clear” system for background checks, which includes healthcare licenses screening

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IMIC Inc. and its circus: meet Simufilam's major clinical research center

IMIC Inc. is a clinical research center based in Palmetto, Florida. It appears to have a critical role in the Simufilam trials, as it is prominent in most the studies with two of its senior staff appear as co-authors of academic publications touting the effectiveness of the drug.

IMIC has a curious history: despite having started operations in 2007, there is barely any sign of activity until around 2016¹², and barely any website traffic until 2019, roughly corresponding to the ramping up of the clinical trials for Simufilam.

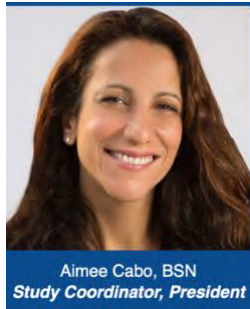


IMIC's website traffic patterns show little/no activity until January 2020, roughly around the start of the 64-person Simufilam trial

¹² This observation is based on the starting dates that IMIC employees posted on LinkedIn: we hardly found anyone who claimed to have worked there prior to 2016

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Aimee Cabo



Aimee Cabo, who co-owns IMIC along with Boris Nikolov, is a “colorful” character and one that we believe might not be the best choice for heading a clinical trials center. She claims to be a nurse, yet a record check at the [Florida Department of Health](#) has failed to show any license¹³. She does have another type of **record, of the criminal type**, with what looks like a felony arrest for possession and consumption of **crack cocaine**^{14 15}(!). In her distant past, she was the central character in “[the Case from Hell](#)”, a legal saga originating from her claim that her stepfather had been repeatedly raping her while a minor. After causing the complete collapse of her family structure, as she and her siblings were taken away from her parents, Aimee took back her claims, “*a recantation supported by the findings of state-appointed experts and a lengthy police investigation*”¹⁶. Regardless of who was ultimately right¹⁷ in this sad story, Aimee has been caught laying in a very important situation and this casts serious doubts on her credibility.

¹³ We checked her name in the list with the spelling used in her public records

¹⁴ The criminal record mentions only “cocaine”. However, Mrs. Cabo specifically mentions using crack cocaine on multiple occasions in her autobiographical book

¹⁵ She also has a past as a former **escort** and **stripper** at [Solid Gold](#), a “gentlemen club” in Pompano Beach, FL.¹⁵

¹⁶ Source: <https://www.miaminewtimes.com/news/the-case-from-hell-and-back-6364110>

¹⁷ Following her recantation, Aimee claimed having caught her “rapist” in an illegally recorded admission of guilt. She either lied when she accused her stepfather or she must have lied in her recantation: either way, her integrity is compromised.

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AIMEE CABO'S CRIMINAL RECORD MENTIONS COCAINE PURCHASE & POSSESSION (2012)



6. RECORD	
Name:	AIMEE CABO-NIKOLYO
Date of birth:	06/09/1974
County:	MIAMI DADE
State:	FL
Offense Details	
Case Number:	132012CF024013A0000X
Court Details	
Case Number:	132012CF024013A0000X
Description:	COUNTY AND CIRCUIT
Disposition:	NO ACTION
Fine:	70950
Level:	FELONY
Offense:	COCAINE POSSESSION
Offense Details	
Case Number:	132012CF024013A0000X
Court Details	
Case Number:	132012CF024013A0000X
Description:	COUNTY AND CIRCUIT
Disposition:	WH ADJ-PROB SP COND
Fine:	70950
Level:	FELONY
Offense:	COCAINE PURCHASE

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--- Private & Confidential ---



Evelyn Lopez-Brignoni MD, IMIC Principal Investigator of the Simufilam trials at IMIC



Evelyn Lopez-Brignoni MD

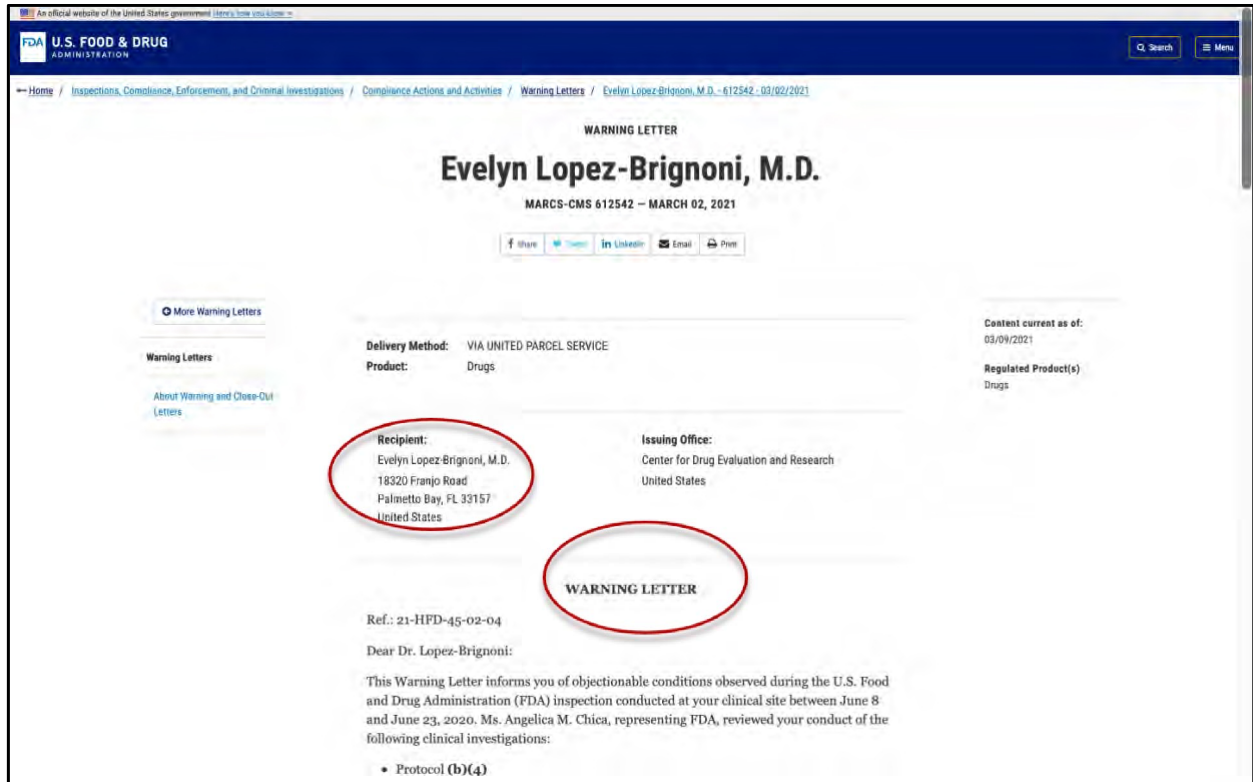
The Principal Investigator for the ongoing Simufilam trial¹⁸, Dr. Brignoni, presumably¹⁹ joined IMIC befriending Aimee Cabo as a court-appointed psychiatrist during a custody trial. She is a Child and Adolescent Psychiatric Specialist, hardly a qualification to treat or diagnose a neurological disease like Alzheimer's. In fact, she was recently hit with a rare and most serious **FDA warning letter for "failing to ensure that the investigation was conducted according to the investigational plan"** and for multiple

¹⁸ Source: clinicaltrials.gov and Simufilam Informed Consent form

¹⁹ Based on Aimee Cabo's autobiography

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serious infractions related to a clinical trial she was overseeing at IMIC²⁰. It is important to point out that a warning letter often signals a **looming FDA enforcement action**, especially when the problems are not promptly remediated (we could find neither a response nor an NDA closeout letter).



²⁰ The letter itself is redacted so we ignore if it relates to the Simufilam study. However, the timeframe would be consistent, and, in any case, the letter casts doubt on the suitability of Dr. Brignoni as a Principal Investigator and of IMIC as a trustworthy institution (IMIC's address appears on the letter).

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Juana Pelegri – PhD aka Pelegrino



Department of Health		FLHealthSource.gov	
JUANA MARCIA PELEGRI			
License Number: BMO1666			
Data As Of 10/15/2021			
License Information	Secondary Locations	Discipline/Admin Action	Continuing Education
Profession	License	License Status	Qualifications
Basic X-Ray Machine Operator	BMO1666	DELINQUENT/	Basic X-Ray Machine Operator
License Expiration Date	License Original Issue Date	Address of Record	
12/31/2015		242 NW LEJEUNE RD MIAMI, FL 33126	

Aimee Cabo describes Juana Pelegri describes her as a “trained clinical psychologist” with expertise in diagnosing Alzheimer’s Disease. On IMIC websites her name is misspelled (see above) and her LinkedIn profile mentions **no PhD nor any academic institution**. She has a page on ResearchGate containing only her name and affiliation with the Grand Canyon University²¹, a mostly online, for profit institution. We found **no evidence of a PhD dissertation** or any academic publication that are typically part of a doctorate. We did find a medical license as a “basic X-Ray machine operator” which **expired in 2015**. Likewise, no trace of a clinical psychologist license.

We fear that, as it seems, Mrs. Pelegri is in fact **not a licensed clinical psychologist** and may be in charge of **diagnosing Alzheimer’s patients in the Simufilam trial**, something for which she would lack qualifications.²²

²¹ We reached out to the university’s registrar’s office to verify her degree, but received no response.

²² This is particularly important as one of our main criticism in the Simufilam trials is that many patients may not have been suffering from Alzheimer’s.

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Boris Nikolov: from rags to riches thanks to Cassava?



Dr Boris Nikolov CCRC

Research Physician, CEO

IMIC is co-led by a Boris Nikolov, a 51-year-old-immigrant from Bulgaria. Mr. Nikolov has a medical license in Bulgaria, but not in the US (though “MD” occasionally appears next to his name²³). Our background checks on Mr. Nikolov in Bulgaria revealed a close business association with a Kristin Valentinova Zaharieva, a real estate investor with **2 criminal records for fraud**²⁴.

In 2012, five years after IMIC commenced operations, Mr. Nikolov filed for bankruptcy, claiming \$450k of negative equity and declaring a yearly income averaging only \$14,000, originating from IMIC.

Two years later, in 2014, Aimee Cabo, Nikolov’s wife and co-owner of IMIC, also filed for bankruptcy claiming equally minimal income²⁵ originating from their clinical practice.²⁶

Interestingly, only a few years later, about when IMIC starts collaborating with Cassava, the financial situation for the couple improves dramatically: D&B reports yearly IMIC income of \$200,000²⁷ since 2018, plus \$319,000 for Franjo Medical Offices²⁸ and \$316,000 for Neuroscience Clinic (now inactive). Moreover, in 2019 the couple appears to have purchased real estate for \$1m and initiated a development project for the realization of a five-story building. We find the **sudden change of fortune remarkable and**

²³ Source: https://clinicaltrials.gov/ct2/history/NCT02727699?V_21=View

²⁴ Source: background check in Bulgaria

²⁵ Official filings report Mrs. Cabo income originating from IMIC at \$3,200 in 2014 after four years of employment

²⁶ Bankruptcy records are publicly accessible at www.pacer.gov

²⁷ D&B provides estimates of sales figures for private businesses. QCM does not guarantee the accuracy of such estimates

²⁸ Possibly a holding company for IMIC real estate assets

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wonder whether it might be related to IMIC's relationship with Cassava and the noted anomalies in the study.

B1 (Official Form 1)(12/11)		United States Bankruptcy Court Southern District of Florida	
Name of Debtor (if individual, enter Last, First, Middle): Nikolov, Borislav S	Name of Debtor (if not individual, enter name of entity):	AMOUNT	SOURCE
All Other Names used by the Debtor in the last 8 years (include married, maiden, and trade names): AKA Boris Nikolov	All Other Names used by the Debtor in the last 8 years (include married, maiden, and trade names):	\$3,579.00	2012 YTD: Husband IMIC Inc
Last four digits of Soc. Sec. or Individual-Taxpayer ID (ITIN) No./Complete EIN (if more than one, state all): xxx-xx-0410	Last four digits of Soc. Sec. or Individual-Taxpayer ID (ITIN) No./Complete EIN (if more than one, state all):	\$24,519.00	2011: Husband IMIC Inc
Street Address of Debtor (No. and Street, City, and State): 13820 Monroe Street Miami, FL	Street Address of Debtor (No. and Street, City, and State):	\$14,588.00	2010: Husband IMIC Inc
ZIP Code: 33176	ZIP Code:		

Mr. Nikolov's public bankruptcy data included minimal income originating from IMIC

Palmetto Bay Office Building Sells for \$1 Million



7 March 2019



18330 SW 97th Ave. in Palmetto Bay. Photo: Google

Address: 18330 SW 97th Ave. in Palmetto Bay

Medical group proposes office building in Palmetto Bay

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Helping you live better.
Now, you can get multiple health benefit plan options from Florida Blue and Trillium Health.

RECOMMENDED
A new medical office building is planned by IMIC Palmetto Bay, Palmetto Bay. (Source: IMIC Palmetto Bay)

COMMERCIAL REAL ESTATE
New medical office

IMIC owners initiate an impressive real estate development project in 2019

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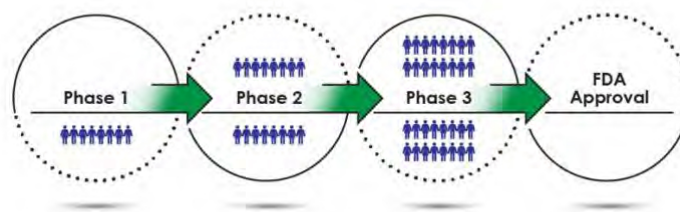
Nature of the drug development process²⁹

Modern drug development is a lengthy, expensive, and complex process, but we can draw some generalizations. The journey starts with the discovery of a new compound, often within academic settings, and the publication of preliminary research describing a proposed mechanism of action, possible benefits, risks, applications etc. (pre-clinical phase). The next stages require significant funding and include:

Phase I, where the drug is tested in healthy volunteers to evaluate the safety before it proceeds to further clinical studies (typically 20-80 subjects).

In Phase II researchers administer the drug to a larger group of patients (typically up to a few hundred) with the disease for which the drug is being developed to initially assess its effectiveness and to further study its safety.

Phase 3 studies typically involve 300 to 3,000 patients assigned to receive either the medication being evaluated or a control group that receives a placebo (a substance that has no therapeutic effect). Researchers design Phase 3 studies – among other things – to demonstrate whether a drug candidate offers a treatment benefit to a specific population. Phase 3 trial results often provide the basis for approval: if the drug is approved, doctors can prescribe the medication for their patients.



²⁹ Source: UNDERSTANDING CLINICAL TRIAL TERMINOLOGY: WHAT'S A PHASE 1, 2 OR 3 CLINICAL TRIAL?

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Mechanics of the alleged Cassava Scheme

Based on the extensive evidence we reviewed, we fear that Cassava has been corrupting the entire drug development process to temporarily inflate Cassava's stock to the market capitalization required for management to maximize its bonuses.

According to our thesis, Cassava may have initially **relied on fraudulent background research** generated by its main author Dr. Wang (who co-and his alleged accomplices concerning Simufilam's mechanism of action and apparent effects. Cassava then proceeded with Phase I and II trials extending the deception and manipulating the trials' design, execution, and outcomes to claim a non-existing clinical efficacy.

Cassava skillfully managed to translate these unsubstantiated claims into stock price appreciation through a well-coordinated campaign to promote its stock and intimidate its critics via social media and various other means.

Cassava's claims on Simufilam

On its [presentation to investors](#) dated September 2021 (and elsewhere) Cassava repeatedly touts the "strength" of its candidate drug Simufilam. We report a selection of its claims:

- *Reduces neurodegeneration and neuroinflammation.*
- *"[...]is **a disease-modifying drug** for AD that also **provides symptomatic improvement**.
[emphasis added]*
- *Simufilam showed **promising treatment effects** in a double-blind, randomized, placebo-controlled study in patients with mild-to-moderate Alzheimer's disease.*
- *Simufilam **improved a panel of validated biomarkers** of disease pathology, neuroinflammation and integrity of the blood-brain barrier.*

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Falsification of background scientific research

On August 18th, 2021, a “Citizen Petition” was filed at the Food & Drugs Administration by Labaton Sucharow, a well-known law firm specialized in SEC whistleblowing. The filing included a number of well-researched documents containing, among other things, a forensic analysis of the background scientific research utilized by Cassava to support its only drug, Simufilam. The report, which we strongly recommend reading, contains dozens of allegedly **doctored photographs**, observations of **statistical anomalies** and other hard evidence strongly suggesting that Simufilam’s **research and laboratory analysis have been forged**, in all likelihood with the intent of falsifying the drug’s mechanism of action and falsely claiming success in reducing certain biomarkers associated with Alzheimer’s Disease.

The petition triggered a 50% stock price collapse and subsequent vehement denials by the Company’s management, yet they provided few convincing arguments or evidence. The City University of New York, Dr. Wang’s sponsoring institution, has recently opened an investigation into the forgery allegations.

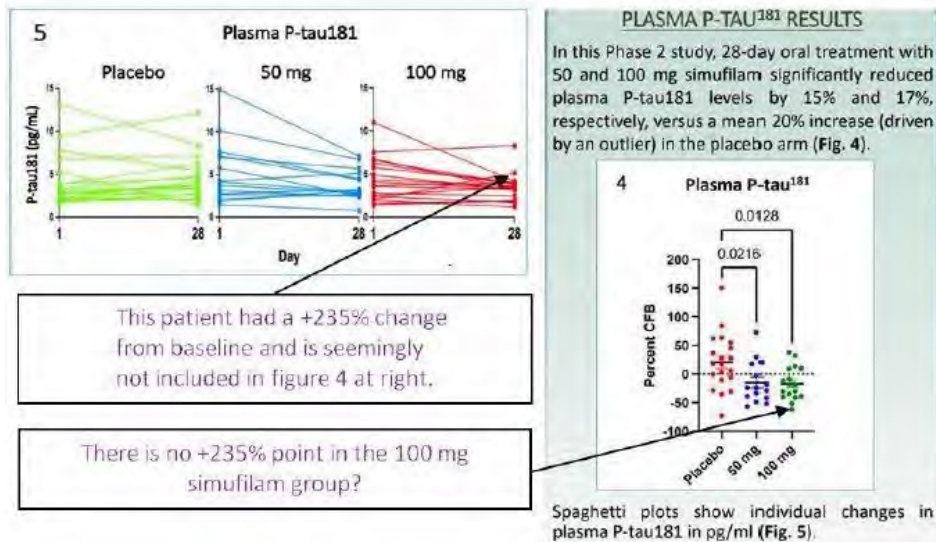
A number of forensic experts including, Dr. Elizabeth Bik and consultants hired by QCM, have systematically **reviewed the documents and confirmed the allegations**, pointing out that Cassava and Dr. Wang could have easily disputed the claims simply releasing the originals of the images in question (for the record: they haven’t)^{30,31}.

³⁰ <https://scienceintegritydigest.com/2021/08/27/cassava-sciences-of-stocks-and-blots/>

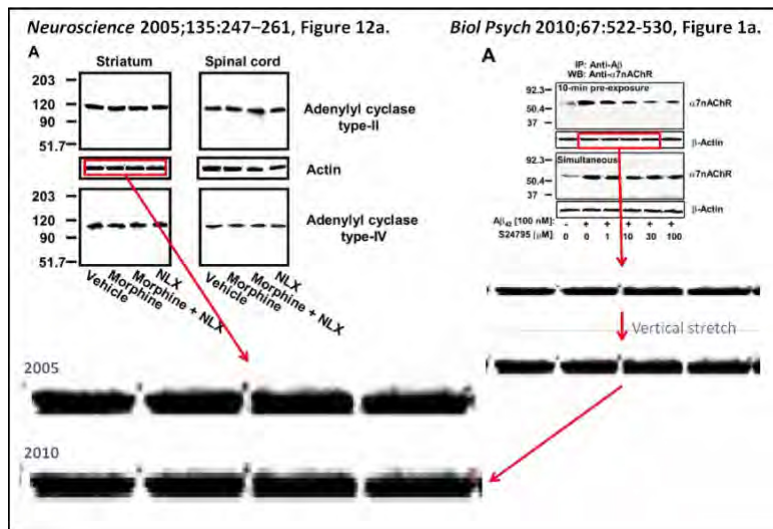
³¹ <https://scienceintegritydigest.com/2021/08/30/cassava-sciences-of-posters-and-spaghetti-plots/>

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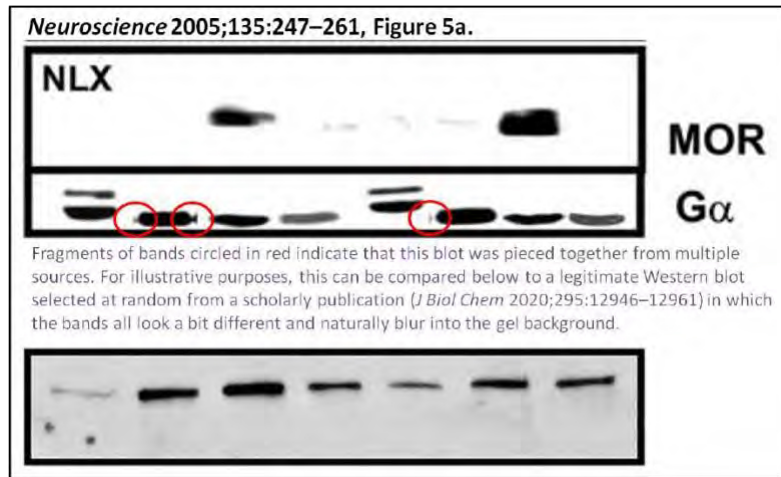
DETAIL OF THE CITIZEN PETITION DEMONSTRATING POSSIBLE FRAUDULENT PRESENTATION OF CLINICAL RESULTS



DETAIL OF THE CITIZEN PETITION DEMONSTRATING POSSIBLE FORGERY IN BIOMARKERS' DATA



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DETAIL OF THE CITIZEN PETITION DEMONSTRATING
POSSIBLE FORGERY IN BIOMARKERS' DATA

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**Alleged Distortion of clinical trials**

Besides the alleged forgery of Cassava's background clinical research, we strongly suspect that Cassava may have similarly distorted the outcome of the trials as well. The mechanism for the alleged falsification of the study may verge on a few critical points:

- Using Phase II trials, normally geared toward establishing safety and dosage, to make **unsubstantiated claims on the efficacy of the drug**
- Allowing **patients who may not suffer from Alzheimer's Disease** into the study, thereby biasing the sample
- Strategically **excluding patients** from the studies who have undesirable clinical outcomes, artificially flattering the efficacy of the drug

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- Comparing the results of the study with other studies having a population with a higher incidence of Alzheimer's patients
- Using questionable, and possibly conflicted, clinical research centers to overlook these anomalies
- Monitoring the trials "in house" only, without the customary third-party scrutiny, which might detect irregular practices

64 persons study (September 2019 – March 2020)

We detected multiple red flags in this study, starting from its inclusion criteria: in other studies we reviewed, only patients with Alzheimer's *per rigorous diagnostic standards* are included. On the other hand, in the recent Cassava 64-person study inclusion criteria specify "diagnosis of dementia due to **possible** or probable Alzheimer's Disease" and allow MMSE cognitive scores as high as 26, which is defined as "normal cognition". With such inadequate enrollment criteria, it is almost certain that there will be patients in the study who do not have Alzheimer's disease (some may have non-Alzheimer's dementia or simple, age-related memory loss). This presents a major problem in the study as any sample of these patients is likely to show better symptoms progression if compared with studies which included exclusively people with certain Alzheimer's: Cassava may be using exactly this discrepancy in pages 20-21 of its presentation to investors to dubiously claim the efficacy of its drug.

In this study, the number of subjects initially in the placebo, 50 mg, and 100 mg cohorts were 22, 21, and 20, respectively. The published biomarkers results, however, were for only 14, 13, and 10 subjects, respectively: turns out that **Cassava has excluded as many as 27 patients out of 64** (42% of total) from the final study results for such implausible reasons as too getting **too many or too few correct answers**³² in the cognitive tests, and for other highly dubious explanations.

³² Other Alzheimer's studies reviewed by our consultants do not exclude patients for this sort of reasons

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		placebo	50mg	100mg	TOTAL
Unit of measure; Participants	Number Analyzed	22 participants	21 participants	21 participants	64 participants
		1 4.5%	1 4.8%	3 14.3%	5 7.8%
Paired Associates Learning total errors (1) (2) Mean (Standard Deviation) Unit of measure; Errors		36% excluded	38% excluded	52% excluded	42% excluded
	Number Analyzed	14 participants	13 participants	10 participants	37 participants
		35.5 (19.65)	31.0 (20.74)	36.1 (18.76)	34.2 (19.7)
<p>[1] Measure Description: Boxes are displayed on the screen and are "opened" in a randomized order. One or more of them contains a pattern. The patterns are then displayed in the middle of the screen, one at a time and the participant must select the box in which the pattern was originally located. If the participant makes an error, the boxes are opened in sequence again to remind the participant of the locations of the patterns. The number of boxes increases progressively to a total of 8.</p> <p>[2] Measure Analysis Population Description: The least impaired patients (11 or fewer errors, representing a ceiling effect) and patients with 54 or more errors (very poor performance suggesting not understanding the task) were removed from the analysis. Also removed were the 3 patients with no detectable drug in plasma, 2 patients with $\geq 25\%$ non-compliance by pill counts, one patient with no baseline test and one who did not understand instructions per rater notes.</p>					

"least impaired patients [...] and patients with 54 or more errors [...] were removed from the analysis." [from Simufilam trial results on clinicaltrials.gov]

We believe that Cassava excluded patients to create artificially promising report on the efficacy of the drug because 1) the groups taking the drug had the largest number of patients excluded, 2) the placebo group had the worst initial cognitive scores and the worst tau/Ab42 (associated with worse prognosis), 3) the fact that Cassava appears to have total discretion on which patients to exclude, without independent oversight, 4) the huge fraction of patients excluded vs initial cohorts (42%) 5) the patients' exclusion seems in conflict with the existing statistical analysis plan. **We deduce that patients may have been excluded "strategically" to fabricate a false efficacy of the drug.** In short: excluding the worst-performing patients from the drug cohort vs placebo would necessarily increase the average cognitive scores of patients in the sample even in total absence of drug efficacy.

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CSF total tau/Aβ42 ratio				
Mean (Standard Deviation)				
Unit of measure: Ratio				
Number Analyzed		22 participants	21 participants	21 participants
		1.20 (0.55)	1.08 (0.50)	1.17 (0.58)
Mini-Mental State Exam (MMSE) ^[1]				
Mean (Standard Deviation)				
Unit of measure: Units on a scale				
Number Analyzed		22 participants	21 participants	21 participants
		23.1 (2.78)	23.0 (2.66)	22.7 (2.67)

[1] Measure Description: The MMSE is a widely used test of cognitive function among the elderly; it includes tests of orientation, attention, memory and visual-spatial skills. It is often used to stage Alzheimer's disease. The scale ranges from 0 to 30. No errors = 30.

The placebo group conveniently shows the worst initial cognitive scores and tau/ab42 ratio

Ongoing 200-persons open label study

We believe there is convincing statistical evidence suggesting that in this study Cassava again **deliberately excluded patients** of Simufilam's effectiveness.

In the comments section of the Citizen Petition, we came across [this anonymous post](#) from a professional well versed in statistical analysis of clinical trials. The post refers to Cassava's research as "likely fraudulent and fabricated". We report here the key points:

To detect any variation in cognitive performance in the subjects taking Simufilam, Cassava has administered a cognitive test³³ to a sample of 50 patients at the beginning of the study, before they started taking the drug. These patients received a follow up cognitive test 6 and 9 months after starting the therapy³⁴.

What is less obvious but can be deduced from Cassava's own statements, is that the **starting cognitive score (baseline) drops over time so that deteriorating cognitive scores can be misrepresented as "improvements"**.

³³ The cognitive test given to patient is the [Adas-Cog 11](#), where higher scores are associated with lower cognitive functioning.

³⁴ The results of the 9 month follow up was made public on September 22nd. The next follow up at 12 months is due around year end.

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Cassava touts a 1.5-point cognitive score improvement from baseline after 6 months of treatment and a 3-point improvement after nine months³⁵. At first glance these numbers would appear impressive. However, looking more closely, we can see that these “improvements” are very much in doubt, as they occurred from **shifting initial scores** (i.e. baselines). The first 1.5-point improvement occurred from a baseline of 15.5 at the start of the trial, to a score of 13.6 in February.

In July, patients improved reportedly 3 points, but the starting baseline, which in February was 13.6, *changed to 16.6*. This has two implications: first, that cognitive scores at 6 and 9 months are essentially the same (13.9 vs 13.6, suggesting virtually no improvement). Second, note that the only way for the baseline to change in February is for the **patients mix to change**. If we believe the company’s statement which limits the dropout rate at less than 10%, it follows that no more than 4 patients may have dropped out and replaced by new ones. Now, for the baseline to have changed to such an extent, the “new” patients’ scores must have been *off the chart* relative to the initial cohort. This can be calculated with precision³⁶: new patients must have had an average cognitive score of 29.3. This is 2 standard deviations above the average of the initial cohort: statistically, the **chances of picking four patients at random with scores so extreme are negligibly small**³⁷, approximately 1 in 160,000.

This can only mean one thing: **Cassava didn’t choose replacement patients at random** (or from the same pool): it is reasonable to assume that they were deliberately selected to **alter the sample’s composition of the study to flatter the performance of the drug**.

It is disturbing that, since similar observations have been posted on Twitter, **Cassava has no longer provided any baseline data** when claiming further improvements on the interim progress of the study,

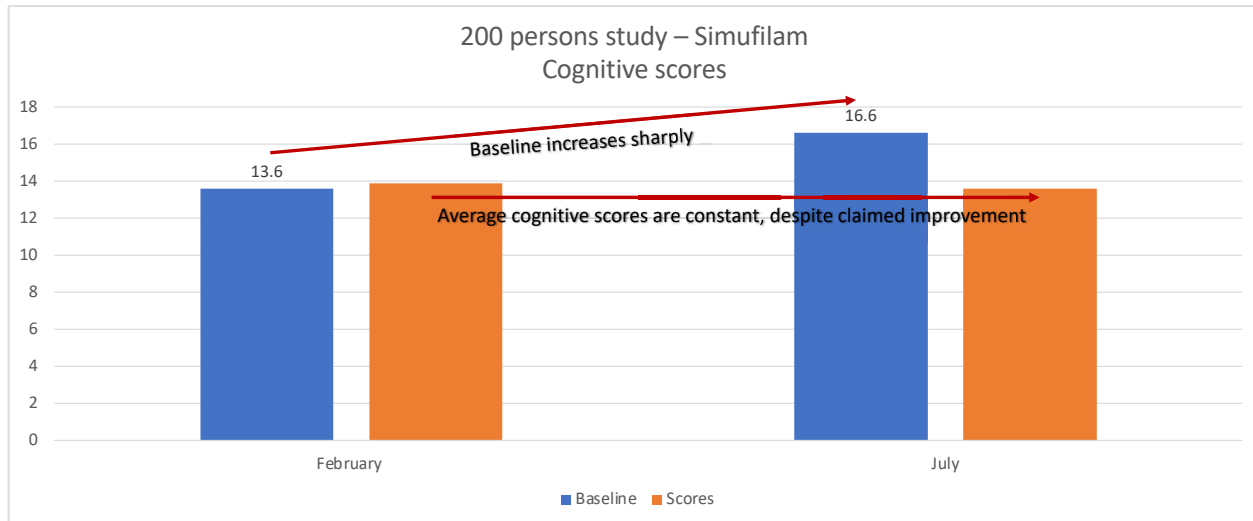
³⁵ <https://www.cassavasciences.com/static-files/13794384-53b3-452c-ae6c-7a09828ad389> [pages 6-9]

³⁶ For the mathematically inclined here is the calculation: score of 4 new patients = $(16.6 \times 50 - 15.5 \times 46) / 4 = 29.3$.

³⁷ The chance of randomly picking a patient with a score of two standard deviations above the mean is 5%. The chance of picking four patients with scores so extreme is $0.5^4 = 0.00063\%$ (1/160,000)

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increasing our suspicion that claimed increases in cognitive performance are again the results of these alleged shenanigans.



Misleading improvement in cognitive scores may be due to replacement of patients causing shifting baseline scores

Cassava close handling of the Simufilam trials and lack of oversight may have facilitated the alleged manipulation of clinical process

Based on talks with our consultants, we understand that a pharmaceutical company sponsoring clinical trials usually outsources the management of this process to a third-party company, a Clinical Research Organization (CRO). At the very least, there should be someone overseeing the relationship between the company and the clinical research site conducting the trials (i.e. the CRA or “monitor” as we saw earlier): this role is typically external to the company as one of its main tasks is to make sure that the study is conducted according to the protocol and to file a complaint with the authorities should significant deviations be detected.

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In Cassava, there are a number of red flags: in some cases³⁸ role of monitor has been assigned to Nadav Friedman, the Company's Chief Medical Officer and Chief Operating Officer. That a company's executive be placed in such a position is both unusual (it's a very tedious job for a senior figure) and worrying³⁹ (it creates a conflict of interest as Cassava is unlikely to blow the whistle on itself). In one case, we learned that **Cassava hired an external monitor that never set foot in the research centers**⁴⁰.

In addition to this, we learned Cassava often reserves itself the right to exclude patients for "*anything that in the opinion of the Investigator would preclude participation in a 2-year study*"⁴¹. Based on our conversations with former employees and with research centers, we understand that such decisions are frequently taken by Cassava's management. Both the lack of third-party oversight we have highlighted as well as the ability to exclude patients (or their data) at will would have enabled Cassava to the alleged manipulations of the study that we saw earlier. More on this in the next sections.

The study doctor, the sponsor company, Advarra, or the FDA may take you out of the study without your permission, at any time, for the following reasons:

- If you do not follow the study doctor's instructions
- If we find out you should not be in the study
- If the study is stopped
- If it becomes harmful to your health

EXCLUSION CRITERIA:

1. Anything that in the opinion of the Investigator would preclude participation in a 2-year study.

Detail of Simufilam's current study's Informed Consent and filing with clinicaltrials.gov showing that Cassava (the "sponsor company") has the faculty to exclude patients at will

³⁸ https://clinicaltrials.gov/ProvidedDocs/03/NCT04079803/Prot_000.pdf

³⁹ This is even more disturbing considering that Mr. Friedman has been sued for securities fraud for making allegedly fraudulent statements regarding Cassava's former drug Remoxy

⁴⁰ Source: former employee. It was unclear whether this happened during the Simufilam or Remoxy trial

⁴¹ <https://clinicaltrials.gov/ct2/show/NCT04388254?term=pti-125&draw=2&rank=3>

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QCM reconnaissance missions

QUINTESSENTIAL RECON AT CASSAVA'S MAIN RESEARCH SITES IMIC & OPTIMUSU

IMIC



OptimusU



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We visited the main clinical research centers involved with Simufilam trials in September 2021: IMIC and OptimusU, our goal was to take a good look at the facilities and, more importantly, to **probe the patient enrollment process of the Simufilam trials**. We hired a number of investigators who presented as candidate trials subjects, but were coached to try to exclude themselves by complaining of benign “memory problems”, typically not associated with Alzheimer’s disease (e.g. forgetting their car keys).

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Our findings shocked us. First, we learned that patients and whoever introduces them to the centers receive **sums of money that many consultants have found excessive**⁴² and potentially leading to conflicts in patient selection. In fact, while chatting in the waiting rooms of these centers, we learned that there are large numbers of “**professional patients**” who go from study to study just to seek these monetary **rewards**. Many “patients” during our visit appeared quite normal (cognitively speaking) and were exchanging tips about what to say to the staff in order to get their study money (!).

Second, during our meeting with the nurse, Mr. Boris Nikolov (head of IMIC) walked into the room and proceeded with what we could describe as a “sales pitch” to join the Simufilam study. Despite mentioning the presence of two more Alzheimer’s studies, **Boris strongly recommended we quickly joined the Cassava one**, mentioning that “*it’s a game changing drug*” that is “*almost certainly going to receive FDA approval*” and that it would be “*the drug he would give to his aging parents*”. We fear such behavior might constitute **undue influence or coercion, which would be a serious violation** of current regulations. Needless to say, our elderly investigators were offered participation⁴³ to the trial despite presumably scoring with flying colors in the preliminary cognitive test.

When asked whether the sponsor is a reputable company, curiously Boris answered that “Cassava only had a handful of employees, but that **its stock price increased manifolds recently (!)**”. When asked whether he held any stock, he became uncomfortable and ultimately did not answer. This raises concerns about the **possibility that Dr. Nikolov might be holding Cassava stock** while being highly conflicted as a researcher involved in the trials of Cassava’s only drug.

⁴² IMIC offered \$200 to one of our investigators over the phone to bring her elderly father. Patients may be given up to \$1,600 to participate to the trial (source: Informed Consent, Cassava/IMIC).

⁴³ This refers to our investigators at IMIC. Those that attended OptimusU were rejected due to having a pacemaker

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During this meeting we learned that IMIC sends all the patients' information to Cassava electronically and that the **decision on whether to keep a patient on the study or not is made by IMIC's principal investigator Dr. Brignoni, but by Cassava itself** (thereby raising the possibility of cherry-picking patients, as we saw earlier). This last observation raises eyebrows because some former employees claim that **IMIC did not use electronic medical records** but recorded everything on paper. Not only is this unusual, inefficient, and prone to error, but it could clearly **facilitate the obfuscation and manipulation** of the results of the trial.

We finally obtained a copy of Cassava/Simufilam Informed Consent document which can be accessed here and that has been thoroughly evaluated by our experts in the latest sections (it contains numerous red flags).

OUR INVESTIGATORS PROBED IMIC AND OPTIMUSU INDUCTION PROCESS POSING AS STUDY CANDIDATES

IMIC



OptimusU



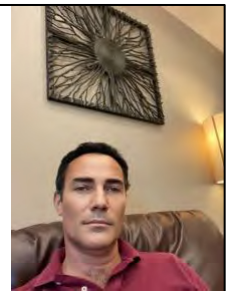
Left: QCM investigator undergoing a clinical interview at IMIC. Right: QCM investigators in OptimusU waiting room

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Business cards obtained by QCM investigators at IMIC

QUINTESSENTIAL RECON: A VISIT TO CASSAVA'S GHOSTTOWN IN AUSTIN, TX



We visited Cassava Sciences' headquarters in Austin just a few days ago and detected minimal activity (we did run, Lindsay Burns who kindly directed us to the lobby...)

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Andrew Jacobson, MD – Consultant clinical trials & medical affairs

Credentials:

- Clin-assist LLC, Medical Affairs Consultant
- Clinical Research Coordinator, Skin Research Institute
- Medical Writer, HCL Technologies
- Consultant, Candesant Biomedical
- Ross University School of Medicine, Doctor of Medicine – MD

Dr. Jacobson's full opinion can be [accessed here](#). Below some highlights of his main findings:

- *The monitor for the sites is Nadav Friedman, the Chief Operating and Medical Officer. This is **unusual** [the role is often performed by individuals not belonging to the sponsor and certainly not by executives]*
- *It seems odd that someone so high up in the executive leadership does this, and he is the only line between what is reported at the sites and what is entered as final data*
- *Dr. Friedman was named as a defendant when Cassava was known as Pain therapeutics and was **caught making fraudulent claims***
- ***Gold standard cognitive tests were not used, the study was not powered to make cognitive improvement statements, and a significant number of subjects in each cohort were discarded from the final results.***
- *The number of subjects initially in the placebo, 50 mg, and 100 mg cohorts were 22, 21, and 20 respectively. The results were for 14, 13, and 10 subjects respectively. This was considerably fewer subjects that had biomarker results and I am wary of a lot of **cherry picking of the results**.*
- *The current 200-person study is open label (not the standard in this field), and the inclusion is a clinical diagnosis of dementia due to *possible* or probable AD. Possible AD indicates that subjects may or will exhibit an atypical course of cognitive decline. This is in stark opposition to other trials that retain more probable AD subjects.*
- *when I initially began to investigate the trial and results, I had a positive impression. But the totality of the past fraudulent activities, the track record of the company, the high likelihood of fraudulent*

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data in the preclinical data on which this is all based, the lack of science behind the proposed mechanism, the lack of ethics, the statements by Cassava leadership, the total lack of transparency and heightened suspicion of altering/massaging data, it [my impression] became more and more negative.

- *I have a very hard time believing that if phase 3 happens on Cassava's timeline, the results will be in line with what is already reported.*

The “Remoxy” affair & alleged securities fraud

Prior to Simufilam, Cassava's only drug was an opioid pain killer called “Remoxy”. After multiple attempts, Remoxy failed to receive FDA approval.

According to the legal proceedings we reviewed, Remi Barbier and Nadav Friedmann were caught making repeated fraudulent statements to investors, essentially leading them to believe that Remoxy was on its way to be approved when, in reality, they knew it was unlikely to receive FDA clearance. As a result of the subsequent FDA rejection, the stock price duly collapsed and shareholders were wiped out. The shockwave was significant enough for the company to fire most of the staff and change its name from “Pain Therapeutics” to “Cassava Sciences”.



Cassava's investors suffered 99% losses as Remoxy failed to obtain FDA approval

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Playing the squeeze? Meet Richard Barry



In June 2021 Cassava announced the addition of Mr. Richard Barry to its Board of Directors, touting that Mr. Barry would be adding “*significant insights around sustainability and governance frameworks*”.

Mr. Barry’s presence should be viewed with concern by Cassava’s shareholders, as he **seems eager to join boards of companies suspected or confirmed to have committed various degrees of fraud.**

Mr. Barry has been of the board of MiMedx, a well-known, fraudulent medical devices company whose former disgraced CEO was convicted of securities fraud⁴⁴.

⁴⁴ Mr. Barry has been appointed to MiMedx board after the exposing of the company’s fraudulent activities. However, sources familiar with Mr. Barry claim that he was involved with, and may have been a shareholder of, MiMedx long before being appointed to the board.

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Mr. Barry currently sits on the board of Sarepta Therapeutics, another pharmaceutical company that has been accused of securities fraud and chastised by the FDA for its approach to the drug approval process (vaguely reminiscent of the situation at Cassava).

Mr. Barry finally sat on the board of Brilliant Light Power (formerly Blacklight Power), a small technology company claiming to generate energy due to an interpretation of quantum mechanics that goes against the accepted laws of physics and that has been heavily criticized by the scientific community for being “pseudoscience”.

It is unclear why Mr. Barry board membership seems overrepresented in controversial companies such as these. Perhaps he hopes to be able to use his clout and connections to support their stocks during turbulent times. No matter what the reason is, his presence on Cassava’s board, given the issues we highlighted, should be paid attention to.

Devastating consequences

The likely devastation of Cassava’ shareholders, if these allegations are proven correct, is only the least negative consequence of Cassava’s conduct. Cassava’s initial research has received extensive funding from the federal government through the NIH: those funds could have been directed toward other ventures with a real chance to provide relief for this terrible disease. Similarly, hundreds of patients are being unnecessarily led into the Simufilam study, being exposed to potentially dangerous chemicals, when they could have participated in studies with a real chance of success.

Finally, Cassava would be serving as a horrible example for other reckless actors willing to follow the same playbook: falsify the initial research, distort the outcome of preliminary trials, get rich through short-term bonuses, then devastate shareholders and patients when the drug inevitably fails phase III trials.

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Conclusion

We believe we have made a convincing case that, together with the documents published in the whistleblower report, leaves very little doubt on Cassava's management behavior and on the **dire prospects** for its Alzheimer's drug Simufilam.

If these allegations are confirmed, Cassava's management may be committing **securities fraud** (again), **FDA fraud** and is in violation of the False Claims Act. Cassava would also be exposed to **crippling litigation** from patients who joined the study unnecessarily. We have accordingly informed all relevant agencies who have received a copy of this report and all the related documents.

A WARNING TO CASSAVA'S MANAGEMENT TEAM AND ITS AFFILIATES

We will not tolerate any harassment via social media or any other means: threats as well as any other violation by the company or its supporters will be immediately made public and forwarded to the relevant federal law enforcement institutions. Legal threats will likewise be crushed swiftly.

Consider yourselves warned.